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Eileen Lucas

EILEEN LUCAS

DATED: January 30, 2008

DECLARATION UNDER 37 C.F.R. §1.132

Province of Alberta
CANADA

I, SAUL KATZ, hereby declare as follows:

1. I am a co-inventor of the invention described in the above-identified patent application (the "Invention") and as such have a personal knowledge of the matters hereinafter stated. I am the founder of Advanced Nutri-Tech Systems Inc., the assignee of the application.

2. I have been in the nutraceuticals and functional foods business since 1989. I founded Advanced Nutri-Tech Systems Inc., the assignee of the application, for the purpose of manufacturing and distributing an embodiment of my invention which is the subject of this application. The SoLo GI™ low glycemic bar available in five flavors is the commercial embodiment of my invention. SoLo GI™ has enjoyed outstanding commercial success, a result of repeat sales indicating that the quality of SoLo GI™ is driving its success rather than its promotion or advertising. SoLo GI™ received the prestigious Golden Egg Award for "The Most Innovative Product" launched in the

United States in 2004 at the 8th Annual Newport Summit - Nutrition & Natural Products Industry Leaders Retreat July 20-22, 2005, held in California. SoLo GI™ was judged against numerous other products, using strict criteria including innovativeness, science, performance, and meeting a need in the marketplace. In relation to popular sports drinks, energy foods and other products, SoLo GI™ has the lowest glycemic index (see Appendix "A" which is a copy of Gretebeck, R.J., Gretebeck, K.A. and Tittelbach, T.J. (2002) *Glycemic Index of Popular Sport Drinks and Energy Foods.* Journal of the American Dietetic Association 102(3):415-417; and Appendix "B" which is a copy of the *Glycemic Index Food List*" at http://www.solo-gi.com/gindex_main.html). SoLo GI™ is currently being used as the benchmark low GI product in five major independent clinical trials conducted by leading scientific institutions including the National Institutes of Health (diabetes-related research); Children's Hospital Oakland Research Institute (pre-gestational diabetes); Children's Hospital Boston and Harvard Medical School (glucose intolerant pregnant women); and Fred Hutchinson Cancer Research Center (link between obesity and cancer). For further reference, see http://www.solo-gi.com/soloresearch_main.html. Sales of SoLo GI™ have occurred at supermarkets and natural food stores across the United States and are available at Amazon.com, meeting a long felt, unsatisfied commercial need.

3. I read the recent Office Action dated October 30, 2007 for this patent application, the patent application and the cited references to Wibert *et al.* (U.S. Patent No. 5,776,887), Sunvold (U.S. Patent No. 6,458,378) and Nidetch (Weight Watchers, pages 218-219). I note that the main rejections are of claims 1, 10, 11, 15 and 16-18 for obviousness over Wibert *et al.*; claims 1, 8, 10 and 11 for obviousness over Sunvold; and claims 1, 10, 11, 13 and 14 for obviousness over Nidetch. I note that the rationale for rejecting the patent claims in view of the cited references includes the following statements:

> It is not seen that Wibert *et al.* teach away from a low glycemic composition, when no showing has been made to show what the GI would have been for Wibert *et al.* as the office is not in a position to do so. Once the rejection has been made, the burden is on Applicants to show that their glycemic index is not shown. Applicants argue that a *prima facie* case of obviousness has not been shown; however, as above, nothing has

> been provided to show what the glycemic index of even the granola bar of Ex. One (page 6 of the Office Action).
>
> ...
>
> Applicants argue that the reference to Sunvold is for pet compositions, and that they often contain ingredients unfit for human consumption. However, as above, nothing has been shown by way of showing what the glycemic index of Sunvold is (page 6 of the Office Action).
>
> ...
>
> Applicants argue that Nidetch does not disclose the claimed GI index. However, as above, Applicants do not say what the GI is. In order for a patent to issue, these references must be overcome, and mere statements do not suffice (page 7 of the Office Action).

4. It is apparent to me from the above Office Action statements that the Examiner requests provision of additional evidence as to what the glycemic indices of the cited prior art compositions would have been in order to demonstrate that the Invention distinguishes the prior art compositions.

5. Based on my experience and knowledge of nutraceuticals and functional foods, I believe that the pending claims of the present application patentably distinguish the cited prior art by virtue that the claimed Invention has a glycemic index which is notably much lower than the glycemic indices of the prior art compositions. I find support in Tables 1 to 3 described below.

6. I personally reviewed the data calculations in Tables 1 to 3, which were conducted by Carla Poirier, who is the Manager of Research and Development for the assignee and a Food Scientist. Ms. Poirier has worked in the field of nutraceuticals, functional foods and food product development since 1998 and has acquired extensive expertise and considerable knowledge pertaining to the Glycemic Index and development of low GI food products since 2005. The following analysis and conclusions reached were arrived at on the basis of my best professional judgment.

7. To assist the Examiner in appreciating the features of the Invention and how it distinguishes the prior art, I have attached Appendix "C" to this declaration. Appendix "C" is a copy of "*Glycemic index of foods: a physiological basis for carbohydrate exchange*" by Jenkins *et al.*, The

American Journal of Clinical Nutrition (March 1981) 34: 362-366. Jenkins *et al.* predates the filing dates of Wibert *et al.* and Sunvold, and the publication date of Nidetch. Jenkins *et al.* pioneered the concept of glycemic index, and relates to a clinical study in which the glycemic indices of different food items were determined by feeding healthy individuals a food item containing 50 g of carbohydrate, measuring the effect on blood glucose levels over two hours, and calculating the area under the two hour blood glucose response (glucose AUC) for the food item. The claimed Invention was scientifically tested and validated in the laboratory of Dr. Thomas Wolever (a co-author of this pioneering GI paper) at the University of Toronto, Toronto, Canada.

8. None of the cited prior art determined or reported the glycemic index of any of the described compositions. The glycemic indices calculated in Tables 1 to 3 below are theoretical, based on the glucose scale, and adapted from the GI values in Table 1 on page 363 of Jenkins *et al.* and "*International table of glycemic index and glycemic load values: 2002.*" Foster-Powell, K., Holt, S.H.A. and Brand-Miller, J.C. American Journal of Clinical Nutrition (2002) 76:5-56. It is my opinion that this is only an approximate method for determining the glycemic indices since additional clinical validation testing is preferred to obtain precise glycemic indices. Published GI values and tables to "predict" the final glycemic index are only as good as the source from which they originated. Jenkins *et al.* provides data which were clinically validated and publicly available before the cited prior art.

9. The glycemic indices for a granola bar of Wibert *et al.*, a pet food composition of Sunvold, and a cheddar cheese muffin of Nidetch were theoretically calculated as set out below. The exemplary formulation described in the Example displayed a glycemic index of 26 +/- 2.7 (33 +/- 3.8). For these theoretical calculations, a suitable margin of error would approximately ± 5 (see also Appendix D).

Table 1. Theoretical GI calculations for a granola bar of Wibert *et al.*

Ingredient	Grams in 100g formula[1]	Grams CHO/100g of	Grams CHO in 100g	% of total CHO[4]	GI value[5]	GI contribution[7]

		ingredient[2]	**formula**[3]			
Rolled oats	40	67	26.8	52.6	49[5]-63[6]	25.8-33.1
Raisins	15	77	11.6	22.7	64	14.5
Novelose starch	10.6	N/A			0	
Nonfat dry milk	7	54	3.8	7.5	36	2.7
Sucrose	7	100	7	13.8	59[5]-65[6]	8.1-9.0
Coconut	6	15	0.9	1.8	12	0.2
Water	5.6	N/A			0	
Peanuts	5	16	0.8	1.6	13	0.2
Vegetable Oil	2	N/A			0	
Vinegar	0.9	N/A			0	
Vitamin Premix	0.5	N/A			0	
Salt	0.2	N/A			0	
Cinnamon	0.2	N/A			0	
TOTAL	**100.0**		**50.9**	**100.0**		**GI = 51.5-59.7**

[1]Obtained from Example 1, Granola Bar, Wibert *et al.*

[2]Adapted from USDA National Nutrient Database.

[3]*Grams in 100g formula* multiplied by *grams CHO/100g of ingredient* and divided by 100.

[4]*Grams CHO in 100g formula* divided by 50.9 and multiplied by 100.

[5]Adapted from Jenkins *et al.*

[6]Foster-Powell *et al.*

[7]*Percentage of total CHO* multiplied by *GI value* and divided by 100.

Table 2. Theoretical GI calculations for a pet food composition of Sunvold.

Ingredient	Grams in 100g formula[1]	Grams CHO/100g of ingredient	Grams CHO in 100g formula[3]	% of total CHO	GI value[4]	GI contribution[5]
Protein	0	N/A			0	
Fat	0	N/A			0	
Grain blend	72.0	75.0[2]	54.0	100.0	60	60
TOTAL	**100.0**	**N/A**	**54.0**	**100.0**		**GI = 60**

[1]As recited in claim 7 in column 10, lines 47-52 of Sunvold - 20% protein, 4% fat, 4% dietary fiber (the lowest of the claimed range of values) and 72% grain mix.

[2]Averaged the three grains (sorghum, barley, corn) to have an approximate level of 75g of carbohydrates per 100 grams of grain.

[3]Adapted from USDA National Nutrient Database.

[4]Adapted from Jenkins *et al.* which lists the mean group GI percentage for cereals as being 60 ± 3.

[5]*Percentage of total CHO* multiplied by *GI value* and divided by 100.

Table 3. Theoretical GI calculations for a cheddar cheese muffin of Nidetch.

Ingredient	Amount in recipe[1]	Grams CHO in recipe[2]	% of total CHO[3]	GI value[4]	GI contribution[5]
All purpose flour	1 cup plus 2 tbsp.	24.8	54.9	69	37.9
Granulated sugar	1 tbsp.	12	26.5	59	15.6
Baking powder	2 tsp.	0	N/A	0	
Cheddar cheese	5 ounces	2	4.4	15	0.7
Skim milk	½ cup	6	13.3	32	4.3
Egg	1	0.4	0.9	0	
Unsalted margarine	2 tbsp.	0	N/A	0	
TOTAL		**45.2**	**100.0**		**GI = 58.5**

[1]Obtained from page 218 of Nidetch.

[2]Adapted from USDA National Nutrient Database.

[3]*Grams CHO in recipe* divided by 45.2 and multiplied by 100.

[4]Adapted from Jenkins *et al.*

[5]*Percentage of total CHO* multiplied by *GI value* and divided by 100.

10. In my opinion, the above results demonstrate that the Invention is distinguished from the prior art compositions. The standard glycemic index scale classifies "low GI" as 55 and below; "medium GI" as 56-69; and "high GI" as 70 and above. The margin of error for these theoretical calculations is approximately ± 5. The composition of Sunvold would be considered to be "low to medium GI" having a theoretical GI as low as 55 or as high as 65. The composition of Nidetch would be considered to be "low to medium GI" having a theoretical GI as low as 53.5 or as high as 63.5. The composition of Wibert *et al.* would be considered to be "low to medium GI" having a

theoretical GI as low as 46.5 or as high as 64.7. Regardless of the "low" ranges of the prior art compositions, the Invention in contrast has an exceedingly low glycemic index.

11. I believe that the pending claims of the present application patentably distinguish the cited prior art by virtue that the claimed Invention has a glycemic index notably lower than the theoretical GIs of the prior art compositions. Claim 1 recites a food item having a glycemic index "lower than 35(50)" and a total carbohydrate content of greater than about 45% by weight. Claim 12 recites a food item having a glycemic index "less than about 30(43)." An exemplary formulation described in the Example displayed a glycemic index of 26 +/- 2.7 (33 +/- 3.8) and 56% carbohydrate content. The Invention was tested by Glycaemic Index Testing Inc. in Toronto using a recognized testing method to obtain an accurate measure of the glycemic index, thereby providing support for the specific glycemic indices recited in the claims.

12. As described in the Background of the present application, prior art formulations have generally reduced the glycemic index of a food by lowering the total carbohydrate content and increasing the protein or fat content; however, it becomes more difficult to maintain a lower glycemic index as the carbohydrate content increases. As the carbohydrate content has reached over 45%, none of the cited prior art formulations has exhibited a glycemic index below 35 (50). In my opinion, the present application describes and claims a food item in which both properties have been successfully achieved – a glycemic index lower than 35(50) and a high carbohydrate content greater than 45%, as explicitly recited in the claims.

13. In my opinion, the food item of the present application has a considerably lower glycemic index compared to the glycemic indices of the prior art formulations, thereby enhancing the health benefits incurred by a low glycemic index. Additionally, the present application offers consumers a very low glycemic food item without unduly reducing the carbohydrate content. The higher carbohydrate content provides an improved taste and texture and a more nutritious snack than prior art formulations. I believe that these specific properties and the overall formulation of the claimed food item patentably distinguish it from the cited prior art formulations.

14. All statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine, or imprisonment, or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the patent application or the patent issuing thereon.

January 25, 2008 Saul Katz

Date Saul Katz

Appendix A

Glycemic index of popular sport drinks and energy foods

RANDALL J. GRETEBECK, PhD, RD; KIMBERLEE A. GRETEBECK, PhD, RN; THOMAS J. TITTELBACH, PhD

Carbohydrate consumption before or during prolonged exercise can enhance endurance performance and after exercise can enhance restoration of glycogen stores (1). For these reasons, athletes are typically advised to increase carbohydrate intake before, during, and after exercise. The type of carbohydrate has recently been included in these recommendations, with the glycemic index used to characterize the blood glucose response to various carbohydrate-containing foods.

The concept of the glycemic index was introduced by Jenkins et al (2) in 1981 as a way of ranking foods on the actual postprandial blood glucose response, compared with a reference food—either glucose or white bread. The glycemic index is calculated by measuring the incremental area under the blood glucose curve, following ingestion of a test food providing 50 g carbohydrate, compared with the area under the blood glucose curve, following an equal carbohydrate intake from the reference food, with all tests being conducted after an overnight fast:

$$\text{Glycemic index} = \frac{\text{Blood glucose area after test food}}{\text{Blood glucose area after reference food}} \times 100$$

Using the glycemic index, or comparison to a reference food, addresses the considerable interindividual variability in the absolute glycemic response to foods. Tables on the measured glycemic index of various carbohydrate-rich foods have been published (3); the benefits of using glycemic index to counsel people remains in debate (4).

The provision of blood glucose to fuel performance during exercise and restore glycogen reserves after exercise is a concern for athletes. In addition, athletes may have difficulty consuming mixed meals or several different food items during or immediately after exercise. Indeed, a number of diet plans and food supplements have been designed for athletes specifically to spare glycogen during exercise and restore glycogen after exercise. In general, low glycemic index carbohydrate foods have been recommended for consumption before prolonged exercise to promote carbohydrate availability. Moderate to high glycemic index carbohydrate foods and drinks are considered appropriate during prolonged exercise (5). High glycemic index carbohydrates are considered the best choice to enhance glycogen storage after exercise by promoting greater glucose and insulin responses.

Although some of these recommendations are debated (5) and further investigation is needed, these recommendations have already been incorporated into some sport nutrition guidelines. Unfortunately, these guidelines can be difficult for athletes to follow, simply because the glycemic index for foods specifically designed for and often used by athletes before, during, and after training and competition have not been measured. Therefore, the purpose of this investigation was to measure the glycemic index of some foods specifically marketed to or used by athletes before, during, and after exercise. We considered 3 categories of sport foods: sport drinks, energy bars, and meal-replacement drinks.

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METHODS

Subjects

The majority of glycemic index studies use 5 to 7 subjects (3). For this study, 5 apparently healthy adult subjects (3 men and 2 women who were recreationally active and reported no health problems) volunteered to participate after approval by the Human Subjects Review Committee at Purdue University, West Lafayette, Indiana.

Measurements

Glycemic index was measured according to Wolever et al (6). Originally, the glycemic index was based on a 50-g glucose solution as the standard (the glycemic index of glucose = 100) (2). White bread may also be used as the standard; however, much of the research concerning carbohydrates and athletic performance is based on the use of glucose solutions (7-9), and most of the sport foods used by athletes are in liquid form. Thus, we defined the glycemic response of glucose as 100, which can be converted to the white bread standard by multiplying by 1.34 (6).

Each subject completed 3 tests using glucose as the reference food, with the mean result being used as the reference to calculate the glycemic index values of the test foods, which were each tested once in random order by all subjects (6). Blood glucose was measured on whole capillary blood samples using One Touch blood glucose meters checked for accuracy using high, low, and normal test solutions available from the manufacturer (Lifescan Inc, Milpitas, Calif.). After an overnight fast, blood glucose was measured at 0, 15, 30, 45, 60, 90, and 120 minutes after the start of consuming the test food. However, if subjects returned to baseline or below baseline before 2 hours, blood sampling was discontinued and the time of return to baseline was determined by interpolation according to Wolever (6). Results were compared

Table
Food products consumed and glycemic index (mean±standard deviation) for 5 recreationally active adults

Product (flavor)	Total weight consumed (g)	Carbohydrate (g)	Protein (g)	Fat (g)	Energy (kcal)	Glycemic index	P value*
Glucose solution	355	50	0	0	200	100	
Sport drinks							
GatorLode[a] (Orange)	243	50	0	0	200	100±21	.601
Gatorade[a] (Orange)	858	50	0	0	200	89±27	.479
XLR8[b] (Orange)	955	50	0	0	200	68±15	.010
Poweraid[c] (Orange)	633	50	0	0	200	65±11	.004*
Cytomax[d] (Orange)	1,183	50	0	0	250	62±15	.007*
Allsport[e] (Orange)	591	50	0	0	200	53±9	.000*
Energy bars							
Cliff bar[f] (Cookies & Cream)	67	50	13	4	290	101±27	.998
Power bar[g] (Chocolate)	72	50	11	2	256	83±25	.256
PR-bar[h] (Cookies 'N Cream)	118	50	33	17	478	81±26	.195
MET-Rx bar[i] (Vanilla)	100	50	28	3	340	74±26	.132
Meal replacements							
GatorPro[a] (Chocolate)	275	50	14	5	304	89±18	.961
Optifuel[h]	355	50	10	0	240	78±18	.070
Ensure® (Vanilla)	283	50	11	7	310	75±23	.098
Boost High Protein[k] (Vanilla)	343	50	23	9	360	59±20	.015
MET-Rx[i] (Vanilla)	1,242	50	84	5	632	58±36	.082
Boost[k] (Vanilla)	283	50	12	5	300	53±9	.000*

*Significantly lower than glucose ($P<.05$) using *t* tests with Bonferroni adjustment for multiple comparisons (Godfrey KAM. *N Engl J Med.* 1985;13:1450-1456).
[a]Gatorade, Chicago, Ill.
[b]Softpac Industries Inc., Plymouth, Minn.
[c]Coca-Cola Company, Atlanta, Ga.
[d]Cytosport, Concordia, Calif.
[e]PepsiCo Inc., Somers, NY.
[f]Cliff bar Inc., Berkeley, Calif.
[g]Power bar Inc., Berkeley, Calif.
[h]Twin Laboratories Inc., Ronkonkowa, NY.
[i]Met=Rx Sibstrate Technology Inc., Irvine, Calif.
[j]Abbott Laboratories, Columbus, Ohio.
[k]MeadJohnson, Evansville, Ind.

with glucose with t tests using the Bonferroni adjustment for multiple comparisons (10). The foods and amounts that were tested are shown in the Table.

RESULTS AND DISCUSSION

Results showing the glycemic index for food products in each category are shown in the Table. The glycemic index may have an important role in athletic performance where the depletion of endogenous carbohydrate is a limiting factor (11); yet, the glycemic index for sport nutrition commercial products has not been readily available. This investigation shows that there is a wide range in glycemic index for sport drinks, energy bars, and meal-replacement drinks. There are a number of attributes of carbohydrate-rich foods that may be of value to athletes including the nutritional value, palatability, portability, cost, gastric comfort, and ease of preparation. This investigation provides an additional piece of information allowing athletes to make more informed choices.

A general indication of the type of carbohydrate in these products is found on the product labels. The most common ingredient was high fructose corn syrup. Major ingredients are listed in descending order on product labels—high fructose corn syrup was the first ingredient listed in some products and appeared much further down the ingredient list for other products. However, the amount of actual fructose in the high fructose corn syrup could not be discerned from the label. Thus, the label on the products did not necessarily provide a good indication of the glycemic response caused by these products. The published glycemic index for fructose is 23 (3), which is lower than all the products tested. The concentration of carbohydrates in the sport drinks evaluated in this investigation ranged from 4% to 20%, and the resulting volumes ingested to provide 50 g carbohydrate ranged from 0.24 to 1.18 L (Table). The American College of Sports Medicine recommends that carbohydrates should be ingested throughout exercise at a rate of 30 to 60 $g.h^{-1}$, keeping the carbohydrate concentration below 10% ($g.100\ ml^{-1}$ of fluid). Thus, the carbohydrate concentration of some products conformed more closely to guidelines for use during exercise than others. Indeed, one product in particular (Gatorlode; Gatorade, Chicago, Ill.) is not intended or marketed for use during exercise but rather for use after exercise to replenish glycogen stores.

The energy contents of the sport drinks tested were relatively similar. The energy bars varied dramatically in energy content (Table) because of the variable amounts of protein and fat. This produced much more variability in the glycemic response. Coleman et al (12) has concluded that liquid and solid carbohydrate feedings consumed during exercise are equally effective in increasing blood glucose and improving performance and also similarly effective in promoting glycogen repletion following exercise. This study showed that the glycemic index of the energy bars did not significantly differ from glucose ($P<.05$) even though they varied widely in energy content based on the 50-g carbohydrate requirement for measuring glycemic index.

Meal-replacement drinks were included in this investigation because they are used increasingly by athletes to supplement a regular diet. These products showed the widest range in the peak glucose response (mean values ranged from a low of 4.7 to a high of 7.3 mmol/L[1] for Met-Rx and Optifuel, respectively) but not in glycemic index, which points to a possible shortcoming in the use of the glycemic index for athletes. The classification of foods according to their glycemic index does not consider the insulin response, which has large effects on metabolism and is functionally significant because it regulates glucose disposal. Therefore, the classification of foods according to their glycemic index is recognized to be rather simplistic. However, its functional significance for describing the metabolic effects of carbohydrate ingestion is certainly better than the prevalent classification of simple or complex carbohydrate. This is especially important for athletes who use sport nutrition commercial products to improve performance or aid in recovery.

APPLICATIONS

The glycemic index provides a relatively new form of nutrition information that some educators have already incorporated into dietary advice for athletes (5). The purpose of this study was to meet the needs of sport nutrition professionals who use commercial products and wish to incorporate the use of glycemic index in their dietary advice for athletes. They cannot do so if they do not know what the glycemic index is. Food labels list the amount of carbohydrate in products, but the amounts of each type of carbohydrate can only be indirectly inferred from a descending list of ingredients by weight. As these results show, products with similar ingredients on their labels can produce a markedly different glycemic index.

[1] To convert mmol/L glucose to mg/dL, multiply mmol/L by 18.0. To convert mg/dL glucose to mmol/L, multiply mg/dL by 0.0555. Glucose of 6.0 mmol/L = 108 mg/dL.

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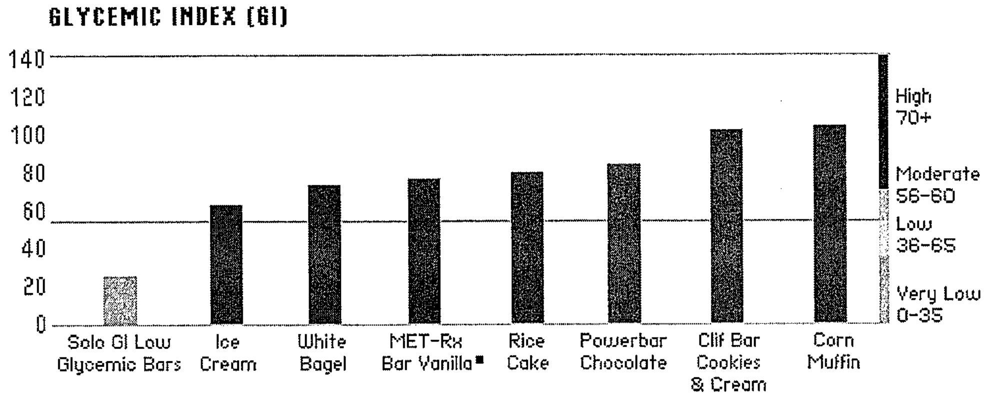
Appendix B

Glycemic Index **Food** List



■Gretebeck RJ, Gretebeck KA, Tittlelback TJ, 2002
Glycemic index of popular sports drinks and energy foods.
Journal of The American Dietetic Association 102(3);415-7

Carbohydrate Food	Glycemic Index Value
SoLo Gi Bars	22 -28 - LOW
All Bran breakfast cereal	30 - LOW
Skim milk	32 - LOW
Yam	37 - LOW
Baked beans	38 - LOW
Spaghetti, cooked al dente	38 - LOW
Sweet potato	44 - LOW
Green grapes	46 - LOW
Carrots	47 - LOW
Macaroni	47 - LOW
Sourdough rye bread	48 - LOW
Sourdough wheat bread	54 - LOW
Pita white bread	57 - MODERATE
Rye bread	58 - MODERATE
Angel food cake	60 - MODERATE
Corn	60 - MODERATE
Taco shells	68 - MODERATE
White bread	70 - HIGH
Bagel	72 - HIGH
Popcorn	72 - HIGH
Kaiser roll	73 - HIGH
French fries	75 - HIGH
Vanilla wafers	77 - HIGH
Jelly beans	78 - HIGH
Rice cakes	82 - HIGH
Pretzels	83 - HIGH
Baked potato	85 - HIGH
Gatorade	89 - HIGH
Cornflakes breakfast cereal	92 - HIGH

Appendix C

Glycemic index of foods: a physiological basis for carbohydrate exchange[1-3]

David J. A. Jenkins,[4] D.M., Thomas M. S. Wolever,[5] M.Sc., Rodney H. Taylor,[6] M.R.C.P., Helen Barker, B.Sc.,[6] S.R.D., Hashmein Fielden,[6] S.R.N., Janet M. Baldwin,[6] M.R.C.P., Allen C. Bowling,[5] Hillary C. Newman,[5] B.A., Alexandra L. Jenkins,[5] and David V. Goff,[5] M.Biol.

ABSTRACT To determine the effect of different foods on the blood glucose, 62 commonly eaten foods and sugars were fed individually to groups of 5 to 10 healthy fasting volunteers. Blood glucose levels were measured over 2 h, and expressed as a percentage of the area under the glucose response curve when the same amount of carbohydrate was taken as glucose. The largest rises were seen with vegetables (70 ± 5%), followed by breakfast cereals (65 ± 5%), cereals and biscuits (60 ± 3%), fruit (50 ± 5%), dairy products (35 ± 1%), and dried legumes (31 ± 3%). A significant negative relationship was seen between fat ($p < 0.01$) and protein ($p < 0.001$) and postprandial glucose rise but not with fiber or sugar content. *Am. J. Clin. Nutr.* 34: 362–366, 1981.

KEY WORDS Carbohydrate exchange, dietary carbohydrate, dietary fiber, blood glucose, diabetes

Introduction

Recent work has suggested that the carbohydrate exchange lists that have regulated the diets of many diabetics for over three decades may not reflect the physiological effect of foods. Such factors as food form (1), dietary fiber (2), and the nature of the carbohydrate (3) have been shown to have a marked influence on the postprandial glycemia and allowances cannot be made for these in lists which take into account only the available carbohydrate content of foods.

Currently, very good blood glucose control has been advocated for diabetics to reduce the incidence of long term complications (4). We have, therefore, fed a range of commonly eaten foods to healthy volunteers so that physiological data on the blood glucose response in man could be obtained to supplement tables based solely on chemical analysis.

Methods

Groups of 5 to 10 healthy nondiabetic volunteers drawn from a pool of 34 (21 male, 13 female; 29 ± 2 yr; 111 ± 3% ideal weight), took 62 foods and sugars in random order after overnight fasts. These were compared with an equivalent amount of carbohydrate taken as glucose. Fifty-six foods were given as 50-g carbohydrate portions calculated from food tables (5, 6). Due to the volume of the remaining six (Table 1), only 25-g portions were provided.

Dry grains, legumes, and vegetables were cooked by boiling in a minimum of water with 2 g salt. To increase palatability all meals included tea made with one tea bag and 50 ml milk so that the total volume of the meal was at least 600 ml. Breakfast cereals were taken with 300 ml milk. 120 g skinned, seedless tomato was added to the spaghetti, rice, bread, millet, buckwheat, and legumes.

Glucose tolerance tests (GTT) were taken over the same time as the respective meals in 550 ml tea with 50 ml milk (except for the cereal GTT where 250 ml tea and 350 ml milk was used). One hundred thirty-two 50 g GTT were performed and a further 23 were matched to test meals with lower carbohydrate content, making one GTT for every two to three foods.

In addition, further tests were performed using glu-

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cose, bread, and lentils to allow completion of dose response curves (Fig. 1).

Meals were eaten over 10 or 15 min at set times in the morning after standard activity and meals on the previous day. Finger prick samples were obtained with Autolet lancets (Owen Mumford Ltd., Woodstock, Oxon) at 0, 15, 30, 45, 60, 90, and 120 min from hands warmed between electric blankets to ensure good blood flow. Blood samples were collected into tubes containing 83 μg sodium fluoride and 250 μg potassium oxalate, and stored on crushed ice or frozen at −20°C before analysis for glucose by a glucose oxidase method (7) (Yellow Springs Instruments, 23AM Glucose Analyser).

Results are given as means ± SEM. The area under the 2-h glucose curve was expressed as a percentage of the appropriate mean GTT value. This value was defined as the "glycemic index". The significance of the percentage reduction in glucose area for each food was calculated using Student's *t* test.

Results

In general, the test meals were well received. Some subjects found the volume of garden peas, soya beans, apples, peanuts, and some of the root vegetables difficult to complete in the allotted time. The number of meals where subjects took longer or ate less than the prescribed amount was small (less than 3%).

The glycemic index for the foods is shown in **Table 1**. Great variation between different foods existed within most of the groups with the exception of dairy products. The group mean percentages in ascending order were: legumes 31 ± 3; dairy products 35 ± 1; fruit 50 ± 5; biscuits 60 ± 3; cereals 60 ± 3; breakfast cereals 65 ± 5; vegetables 65 ± 14; sugars 71 ± 20; root vegetables 72 ± 6.

The dose response curves for glucose, bread, and lentils are shown in **Figure 1**. Although there was a marked tendency for all the curves to flatten above 50 g carbohydrate, the differences in terms of glycemic

TABLE 1
Glycemic index: the area under the blood glucose response curve for each food expressed as a percentage of the area after taking the same amount of carbohydrate as glucose (result are means of 5 to 10 individuals)

Grain, cereal products			Vegetables			Fruit		
Buckwheat	51 ± 10*	(5)	Broad beans (25)¶	79 ± 16	(6)	Apples (golden delicious)	39 ± 3†	(6)
Bread (white)	69 ± 5†	(10)	Frozen peas	51 ± 6†	(6)	Banana	62 ± 9*	(6)
Bread (wholemeal)	72 ± 6†	(10)	Root Vegetables			Oranges	40 ± 3†	(6)
			Beetroot (25)¶	64 ± 16	(5)	Orange juice	46 ± 6†	(6)
Millet	71 ± 10‡	(5)	Carrots (25)¶	92 ± 20	(5)	Raisins	64 ± 11‡	(6)
Pastry	59 ± 6*	(5)	Parsnips (25)¶	97 ± 19	(5)			
Rice (brown)	66 ± 5†	(7)	Potato (instant)	80 ± 13	(8)	Sugars		
Rice (white)	72 ± 9§	(7)	Potato (new)	70 ± 8*	(8)	Fructose	20 ± 5†	(5)
Spaghetti (wholemeal)	42 ± 4†	(6)	Potato (sweet)	48 ± 6†	(5)	Glucose	100 ±	(35)
			Swede (25)¶	72 ± 8‡	(5)	Maltose	105 ± 12	(6)
Spaghetti (white)	50 ± 8|	(6)	Yam	51 ± 12§	(5)	Sucrose	59 ± 10§	(5)
Sponge cake	46 ± 6†	(5)	Dried legumes			Dairy products		
Sweetcorn	59 ± 11§	(5)	Beans (tinned, baked)	40 ± 3†	(7)	Ice cream	36 ± 8|	(5)
						Milk (skim)	32 ± 5†	(6)
Breakfast cereals			Beans (butter)	36 ± 4†	(6)	Milk (whole)	34 ± 6†	(6)
All-Bran	51 ± 5†	(6)	Beans (haricot)	31 ± 6†	(6)	Yoghurt	36 ± 4†	(5)
Cornflakes	80 ± 6‡	(6)	Beans (kidney)	29 ± 8†	(6)			
Meusli	66 ± 9§	(6)	Beans (soya)	15 ± 5†	(7)	Miscellaneous		
Porridge Oats	49 ± 8|	(6)	Beans (tinned, soya)	14 ± 2†	(7)	Fish fingers	38 ± 6†	(5)
Shredded Wheat	67 ± 10‡	(6)	Peas (blackeye)	33 ± 4†	(6)	Honey	87 ± 8	(6)
Wheatabix	75 ± 10‡	(6)	Peas (chick)	36 ± 5†	(6)	Lucozade	95 ± 10	(5)
			Peas (marrowfat)	47 ± 3†	(6)	Mars bar	68 ± 12‡	(6)
Biscuits			Lentils	29 ± 3†	(7)	Peanuts (25)¶	13 ± 6†	(5)
Digestives	59 ± 7*	(6)				Potato crisps	51 ± 7†	(6)
Oatmeal	54 ± 4†	(6)				Sausages	28 ± 6†	(5)
Rich Tea	55 ± 4†	(6)				Tomato soup	38 ± 9*	(5)
Ryvita	69 ± 10‡	(7)						
Water	63 ± 9*	(6)						

Significance of difference from equivalent glucose load: * = $p < 0.01$; † = $p < 0.001$; ‡ = $p < 0.05$; § = $p < 0.02$; | = $p < 0.002$; ¶ Only 25 g carbohydrate portion given.

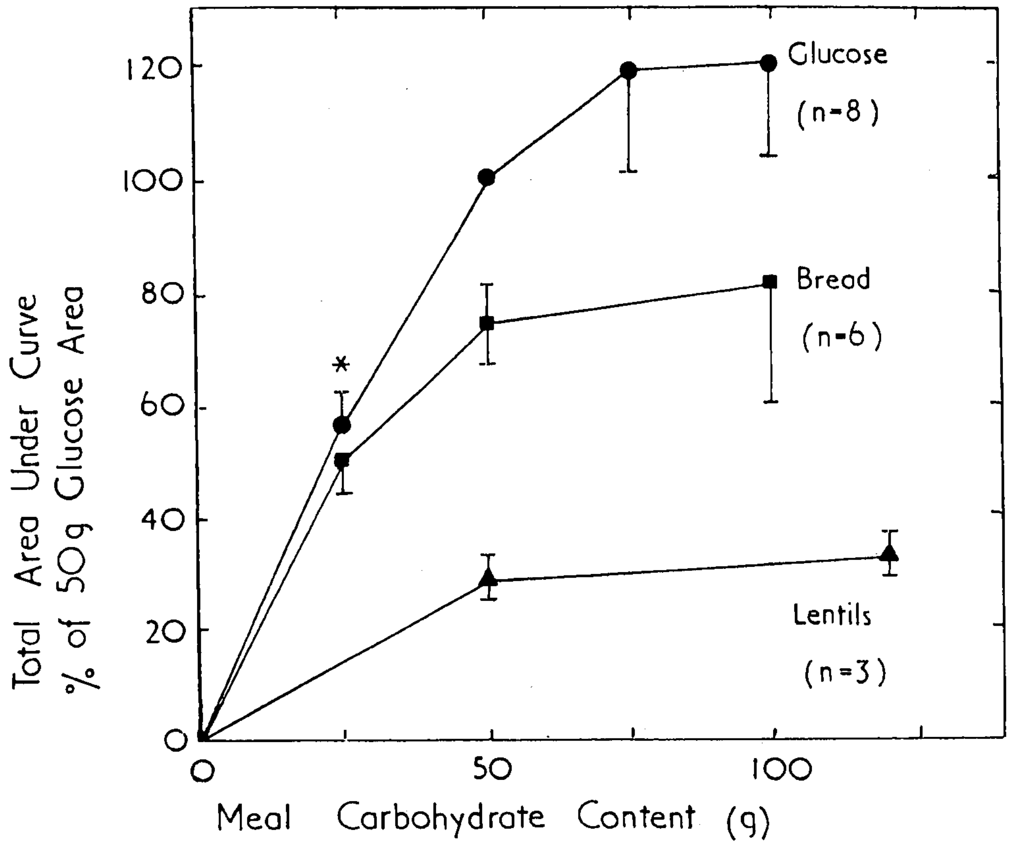

FIG. 1. Dose response curve to glucose, wholemeal bread, and lentils in healthy volunteers. * represents 11 subjects.

index were greater rather than smaller. On the other hand, at 25 g no significant difference was seen between bread and glucose. Thus, the glycemic index of those foods where only 25 g was taken (i.e., broad beans, beetroot, carrots, parsnips and swede) may be artificially high by comparison with 50-g portions.

A significant negative relationship was seen between fat ($r = -0.386$, $p < 0.01$) and protein ($r = -0.523$, $p < 0.001$) content of the foods and the glycemic index (**Fig. 2**). There was, however, no relationship between glycemic index and dietary fiber or sugar content.

Discussion

The results demonstrate great inequality in the extent to which different carbohydrate sources raise the blood glucose and indicate that simple carbohydrate exchanges based on chemical analysis do not predict the physiological response. Great differences were seen not only between but also within most of the food groups, e.g., among cereals the glycemic index for wholemeal bread was 72% while for wholemeal spaghetti it was 42%, and amongst the root vegetables, parsnips were 97% compared with 48% for sweet potatoes.

One striking feature was that the high carbohydrate foods with the lowest glycemic index were those eaten commonly by the poor in Western countries or the inhabitants of large parts of Africa and Asia. They included oatmeal porridge, spaghetti, buckwheat, yam, sweet potato, and dried leguminous seeds.

It is tempting to speculate that positive selection may be operating to eliminate carbohydrate-rich, low glycemic index foods

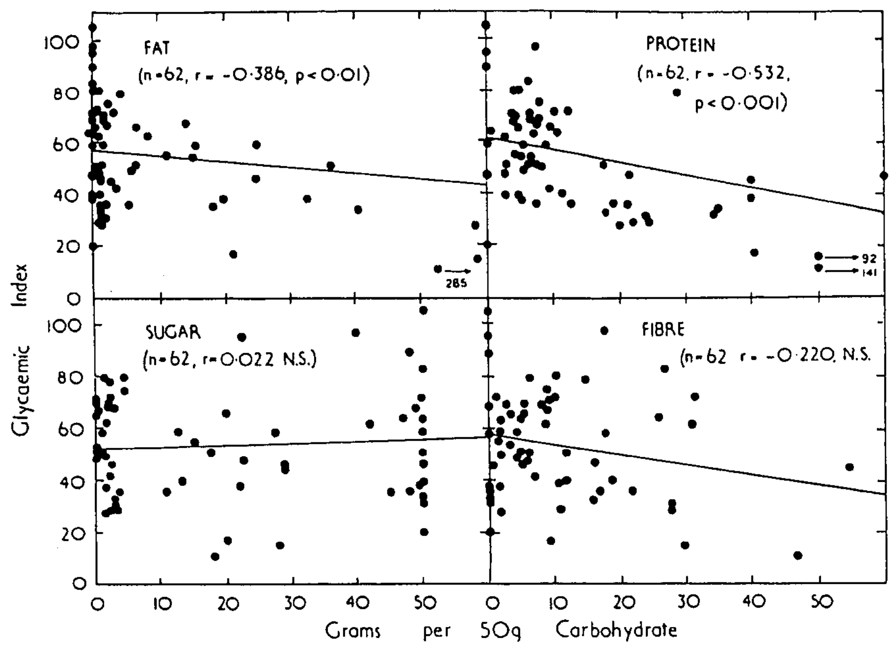

FIG. 2. Relationship of fat, protein, sugars, and fiber content of 62 foods to the glycemic index of 50-g carbohydrate portions.

from affluent Western nutrition. At the same time, certain foods that cause relatively large rises in blood glucose such as rice, millet, and bananas are nevertheless preserved in diets of less developed communities.

Surprisingly, no significant relationship was seen between glycemic index and dietary fiber. This may have been due to the fact that many of the high fiber foods were wheat products and wheat fiber has little effect on blood glucose (2). Indeed, there was little difference between the high fiber wholemeal bread (8), spaghetti and brown rice and their low fiber white counterparts.

The other major high fiber group was the legumes and by comparison with the cereals, they were remarkable in how little they raised the blood glucose. The mean glycemic index for cooked whole grains, breads, spaghetti and porridge was 59% compared with 31% for the legumes ($p < 0.001$). In this context, it is of interest that the dietary fibers, guar and tragacanth, from leguminous plants, are known to flatten the blood glucose rise after 50 g glucose more markedly than other forms of dietary fiber and fiber analogues (2).

Sugar content was not related to blood glucose response even though absorption may have been more rapid. This is presumably due to the very small rise (20%) produced by fructose (9) and reflected in the response to sucrose. On the other hand, both fat ($p < 0.01$) and protein ($p < 0.001$) showed a significant negative correlation with glycemic index. Fat is known to delay gastric emptying (10) and protein stimulates insulin secretion (11). However, it is not clear whether these actions or a direct effect of fat and protein in reducing the digestibility of food were responsible for the negative correlation. The similarity seen here between the blood glucose response to whole and skimmed milk suggests that the action of fat may not be simple. Furthermore the action of protein is not readily explained since addition of cottage cheese to wholemeal bread had little effect on the blood glucose response (D.J.A. Jenkins, T.M.S. Wolever, R.H. Taylor, and A.C. Bowling, unpublished observations).

There are very few studies comparing the effects of different foods on blood glucose. A comparison of glucose, potato, bread, rice, and corn (3) showed that the nature of the starch itself may be of major importance in

determining the glucose and insulin response and may be part of the reason for differences seen here between cereals and legumes. Apart from variations amongst individuals taking part in the tests, small differences in the nature of the food or its preparation may also have a great influence on the glycemic response. Nevertheless, in the only trial (12) where a sufficient number of foods (12) was tested to allow comparison, the results correlated significantly with our own for the 10 items common to both studies (glucose, sucrose, fructose, bread, porridge, rice, potato, orange, apple, dried pea: $r = 0.823$, $p < 0.001$). However, the greatest similarities were between the sugars for which, unlike foods, no differences in composition or preparation would exist.

The dose response curves for glucose, bread, and lentils demonstrated that when more than 50 g carbohydrate from any source was taken, the increase in glycemic index was smaller than expected. However, the relative differences between the three carbohydrate sources was, if anything, accentuated indicating that simple increases in meal size would not invalidate tables based on 50-g carbohydrate portions.

We believe, therefore, that classification of foods according to their effects on blood glucose is useful due to the differences in response which exist. The ability to prescribe for diabetics a varied diet of low glycemic index foods is especially appropriate at a time when more emphasis is being placed on "tight" blood glucose control (4) in order to avoid long-term complications. The same range of foods may be useful, both for postgastric surgery patients who suffer from hypoglycemia after large rises in blood glucose and insulin after meals, and also for patients with carbohydrate-induced hyperlipidemia. On the other hand, patients with reduced absorptive capacity or diabetics on the brink of insulin-induced hypoglycemia may benefit from foods with a higher glycemic index.

The authors thank all the volunteers and especially Mr. Michael Hogan of Speywood Laboratories who additionally gave much help and provided the malted oatmeal biscuits used in this study. We also thank Mr. J. H. Fulljames of Snakpak Products Ltd. for provision of peanuts.

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Appendix D

G.I. Testing

Glycaemic Index Testing Inc.
135 Mavety St., Toronto,
Ontario, Canada M6P 2L8
Tel: (416) 978-5556
FAX: (416) 769-7210

11 May, 2001

Jing Lu,
New Era Nutrition,
New Era Place,
10519 - 99th Ave.,
Edmonton, Alberta T5K 0E7

Dear Jing,

Here is the final report for the GI test of the Lemon Bar. Please let me know if you would like to have an electronic copy of the Lotus 123 spreadsheet containing in the data. If you have any questions or comments about the report, please don't hesitate to contact me.

Yours sincerely,

Tom

Thomas MS Wolever, MD, PhD,
President.

G.I. Testing

Glycaemic Index Testing Inc.
135 Mavety St., Toronto,
Ontario, Canada M6P 2L8
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New Era Nutrition
FINAL REPORT

Determination of Glycemic Index

GI Lemon Bar

DISCLAIMER

GI Testing has taken due care to ensure the accuracy of the results provided in this report. However, the results of glycemic response tests in human subjects are subject to biological variability and may vary depending on the methods used. Thus, these results may not be able to be reproduced exactly either by GI Testing or by others.

Table 2: Palatability and Glycemic Index*

Test Meal	Palatability (mm)	Glycemic Index	
		Bread=100	Glucose=100*
White Bread	80	100[a]	71 (H)
Lemon Bar	58	33[b]	24 (L)

[ab] Means with different letter superscripts differ significantly, $p<0.05$.
* Category from GI Factor (Brand-Miller et al.): H=high GI; M=medium GI; L=low GI.

Palatability

The Lemon Bar tended to be less palatable than bread, but the difference was not statistically significant (Column labeled "Pal" on sheet with graphs).

Blood Glucose Responses

The blood glucose responses are shown on the page showing the graphs with significance determined by paired t-test.

Mean fasting blood glucose was identical before the Lemon Bar and bread. Blood glucose concentrations and increments after the Lemon Bar were significantly less than those after bread at every time point from 30 to 120 minutes. The area under the curve and the GI value of the Lemon Bar were significantly less than those after bread.

SUBJECT DETAILS

ID	Sex	Age (y)	Height (cm)	Height (in)	Weight (kg)	Weight (lb)	BMI
1	M	34	173.0	68.1	85.9	189	28.70
27	F	23	170.2	67.0	58.6	129	20.23
31	F	52	162.0	63.8	58.6	129	22.33
32	F	24	175.0	68.9	60.5	133	19.76
36	M	34	190.5	75.0	84.1	185	23.17
39	F	69	161.3	63.5	55.5	122	21.33
46	F	18	170.2	67.0	60.0	132	20.71
47	F	40	167.6	66.0	56.1	123	19.97
49	F	26	160.0	63.0	46.1	101	18.01
51	F	26	163.0	64.2	54.0	119	20.32
Mean		34.6	169.3	66.6	61.9	136.3	21.45
SEM		4.9	2.9	1.1	4.1	8.9	0.92

Within-subject variation of standard tests

INCREMENTAL AREA UNDER THE CURVE

ID	WB#1	WB#2	WB#3	Mean	SD	CV
1	173.1	121.8	188.7	161.2	35.0	21.7
27	126.3	169.7	205.1	167.0	39.5	23.6
30	318.1	352.1	330.3	333.5	17.2	5.2
33	100.9	268.9	197.3	189.0	84.3	44.6
36	187.7	216.8	131.1	178.5	43.6	24.4
39	270.0	281.9	220.7	257.5	32.4	12.6
46	227.8	223.2	195.2	215.4	17.6	8.2
47	244.9	239.5	188.9	224.4	30.9	13.8
49	126.2	151.9	240.0	172.7	59.7	34.6
51	139.9	316.3	223.8	226.7	88.2	38.9
Mean	191.5	234.2	212.1	212.6	44.8	22.8
SEM	22.6	23.1	16.0	16.7	7.9	4.2

ANOVA	Source	SS	df	MS	F	p
	Order	9159.953	2	4579.98	1.97547	0.16764
	Subject	75468.21	9	8385.36	3.61683	0.00974
	Error	41731.73	18	2318.43		
	Total	126359.9				

Dates (dd/mm/yy) of White Bread standard tests

ID	WB#1	WB#2	WB#3
1	09/03/01	16/03/01	30/04/01
27	01/03/01	20/03/01	12/04/01
31	13/03/01	24/04/01	08/05/01
32	13/03/01	24/04/01	26/04/01
36	28/03/01	02/04/01	12/04/01
39	19/03/01	30/03/01	10/04/01
46	29/03/01	12/04/01	08/05/01
47	05/03/01	28/03/01	12/04/01
49	02/03/01	19/03/01	16/04/01
51	26/03/01	09/04/01	24/04/01

Lemon Bar

ID	Pal	0min	15min	30min	45min	60min	90min	120min	AUC	GI
1	72.5	4.09	4.72	5.38	4.48	4.13	4.57	4.10	50.1	31.1
27	38.5	4.49	4.54	5.54	5.82	4.49	4.28	4.79	39.1	23.4
31	91.5	4.93	4.81	5.73	6.90	5.94	5.20	5.32	77.4	23.2
32	64	4.50	5.29	6.43	4.15	4.27	4.87	4.76	51.5	27.2
36	11	4.33	4.52	5.25	5.66	5.44	4.96	4.52	83.3	46.7
39	87	4.94	6.07	6.82	7.06	6.39	5.56	5.11	130.7	50.8
46	77	4.48	5.00	6.31	5.17	4.14	5.11	4.77	63.8	29.6
47	16	4.58	5.05	6.61	6.08	5.53	5.32	4.42	101.6	45.3
49	65	4.17	4.40	5.86	4.82	4.55	4.60	4.64	67.1	38.9
51	52	4.37	4.52	5.69	4.99	4.32	4.18	4.30	31.0	13.7
Mean	57.5	4.49	4.89	5.96	5.51	4.92	4.87	4.67	69.6	33.0
SEM	8.82	0.09	0.16	0.17	0.31	0.26	0.14	0.12	9.53	3.8
p	0.083	0.967	0.494	0.000	0.000	0.000	0.001	0.017	0.000	0.000

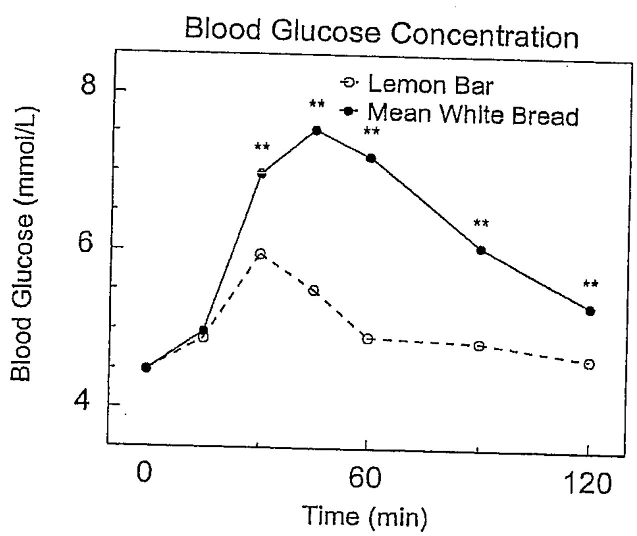
INCREMENTS

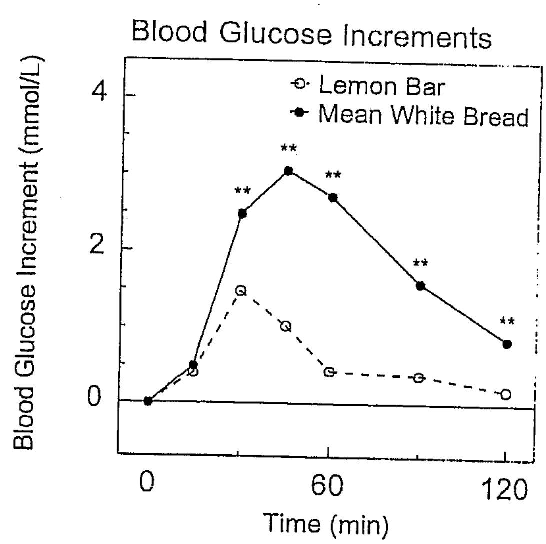
0min	15min	30min	45min	60min	90min	120min
0	0.63	1.29	0.39	0.04	0.48	0.01
0	0.05	1.05	1.33	0.00	-0.21	0.30
0	-0.12	0.80	1.97	1.01	0.27	0.39
0	0.79	1.93	-0.35	-0.23	0.37	0.26
0	0.19	0.92	1.33	1.11	0.63	0.19
0	1.13	1.88	2.12	1.45	0.62	0.17
0	0.52	1.83	0.69	-0.34	0.63	0.29
0	0.47	2.03	1.50	0.95	0.74	-0.16
0	0.23	1.69	0.65	0.38	0.43	0.47
0	0.15	1.32	0.62	-0.05	-0.19	-0.07
0	0.40	1.47	1.03	0.43	0.38	0.18
	0.12	0.14	0.24	0.20	0.11	0.06
	0.574	0.000	0.000	0.000	0.001	0.012

Mean White Bread

ID	Pal	0min	15min	30min	45min	60min	90min	120min	AUC
1	93.8	4.27	4.56	6.18	7.20	6.79	5.08	4.30	161.2
27	67.8	4.45	4.68	6.32	7.00	6.87	5.57	5.07	167.0
31	86.0	5.05	5.04	7.16	9.06	9.61	8.53	7.32	333.5
32	86.2	4.18	5.08	6.73	6.58	6.19	5.51	5.23	189.0
36	88.3	4.70	4.78	6.28	7.69	7.76	5.86	5.04	178.5
39	39.5	5.06	5.36	7.90	8.36	8.08	7.18	7.03	257.5
46	85.0	4.38	5.08	7.02	7.60	6.84	6.05	5.17	215.4
47	92.7	4.54	5.53	7.59	7.89	7.21	5.95	5.30	224.4
49	95.2	4.20	4.52	7.15	6.77	5.84	5.51	4.81	172.7
51	65.2	4.02	5.14	7.34	7.20	6.82	5.53	4.16	226.7
Mean	80.0	4.49	4.98	6.97	7.54	7.20	6.08	5.34	212.6
SEM	5.5	0.11	0.11	0.18	0.24	0.34	0.32	0.33	16.7

0min	15min	30min	45min	60min	90min	120min
0	0.29	1.91	2.93	2.52	0.81	0.03
0	0.23	1.87	2.55	2.42	1.12	0.62
0	-0.01	2.11	4.01	4.56	3.48	2.27
0	0.90	2.55	2.40	2.01	1.33	1.05
0	0.08	1.58	2.99	3.06	1.16	0.34
0	0.30	2.84	3.30	3.02	2.12	1.97
0	0.70	2.64	3.22	2.46	1.67	0.79
0	0.99	3.05	3.35	2.67	1.41	0.76
0	0.32	2.95	2.57	1.64	1.31	0.61
0	1.12	3.32	3.18	2.80	1.51	0.14
0	0.49	2.48	3.05	2.72	1.59	0.86
	0.13	0.18	0.15	0.25	0.24	0.23





Glycaemic Index Testing, Standard Protocol
DETERMINATION OF THE GLYCAEMIC INDEX OF FOODS

OBJECTIVE

To provide confidential and scientifically valid assessment of the glycaemic index (GI).

SUBJECTS

Inclusion criteria

Subjects are males or non-pregnant females aged 18-75 years and in good health.

Exclusion/withdrawal criteria

- age less than 18 years
- known history or AIDS, hepatitis, diabetes or a heart condition
- subjects using medications or with any condition which might, in the opinion of Dr. Wolever, the president of GI Testing, either: 1) make participation dangerous to the subject or to others, or 2) affect the results
- subjects who cannot or will not comply with the experimental procedures or do not follow GI Testing safety guidelines.

Number of subjects

Normally, 10 subjects are studied with all subjects testing all the foods in a series. More subjects may be studied to detect small differences, if results are desired quickly or for protocols requiring more than one group of subjects.

Number of tests done by each subject

An individual subject will normally do 1-2 tests per week.

PROCEDURES

Subjects are studied between 7:00 and 9:30am after an overnight fast of 10-14h. On each test occasion the subject is weighed, and a fasting blood sample is obtained by finger-prick. Then the subject starts to consume a test meal. At the first bite a timer is started and additional blood samples are taken at 15, 30, 45, 60, 90 and 120 min. Before and during the test, a blood glucose test record is filled out with the subject's initials, ID number, date, body weight, test meal, beverage, time of starting to eat, time it took to eat, time and composition of last meal, and any unusual activities. During the 2 hours of the test, subjects remain seated quietly.

Blood Samples

Each blood sample consists of 2-3 drops of blood obtained by finger-prick. Blood samples are taken into flat-bottomed 5ml plastic tubes with a push cap containing a small amount of sodium fluoride and potassium oxalate as an anticoagulant and preservative. Glucose analysis is done using a YSI model 2300 STAT analyzer (Yellow Springs, OH).

Test Meals

Test meals consist of portions of the test food or white bread containing exactly 50g glycaemic carbohydrate (total carbohydrate minus dietary fiber). Other non-glycaemic carbohydrates such as sugar alcohols, fructo-oligosaccharides and resistant starch, are not included as glycaemic carbohydrate. Appropriate nutrient analytic data is required for determining portion sizes. If the client cannot provide acceptable data, or agrees to have the foods analyzed, Glycaemic Index Testing Inc. will arrange for food analysis by a recognized independent laboratory, the cost of which will be charged to the client. Each test meal is taken with a standard drink. Subjects can choose to have one or 2 cups water, tea or coffee with or without 2% milk and artificial sweetener; the drink the subject chooses the same for all tests done by that subject. Breakfast cereals are served with 1 cup 2% milk. Test meals are consumed within 10 minutes.

Study Design

Subjects are studied for a series of tests including a certain number of test foods and at least 3 standard white bread tests. White bread is arbitrarily assigned a GI value of 100 - 3 tests are needed to provide a representative mean standard response for each subject. If the test foods include breakfast cereals, then the effect of the milk added to the breakfast cereal is controlled for by an additional test of white bread plus 1 cup milk. In addition, a test of 50g glucose is recommended as a positive control. Generally, the standard white bread tests are done at the beginning, middle and end of a series with the order of the other foods randomized. If more than 12 foods are tested, one white bread standard will be included for every 3-4 test foods. Tests from more than one client may be included in one series, but one white bread test will always be done for every 4-5 foods tested by each subject.

Statistical Analysis

Incremental areas under the blood glucose response curves (AUC), ignoring area below fasting, are expressed as a % of the mean AUC for the 3 bread tests taken by the same subject. The mean of the resulting values is the GIwb (white bread = 100). The GIwb values are adjusted to the GI (glucose = 100) by dividing by 1.4. Results for all foods in a series will be compared by repeated measures ANOVA using the Neuman-Kuels method to adjust for multiple comparisons. Each food will be compared to white bread by paired t-test.

Time to Completion

The time to complete tests cannot be guaranteed, but is expected to be about 1 month plus 1 week per test food after tests have started.

Informed Consent

The GI Testing protocol has been approved by the Western Institutional Review Board® which meets all requirements of the US Food and Drug Administration (FDA), the Department of Health and Human Services (DHHS), the Canadian Health Protection Branch (HPB), Canadian Institutes for Health Research (CIHR) and the European Community Guidelines. Informed consent is obtained from all subjects for each series of tests they participate in.